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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,649

06/04/2002

Pierre Belhumeur

1051-1-019

6750

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01/12/2010

EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

01/12/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 09/980,649	<b>Applicant(s)</b> BELHUMEUR ET AL.	
	<b>Examiner</b> TAEYOON KIM	<b>Art Unit</b> 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 3,5,6 and 8-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3,5,6 and 8-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Applicant's amendment and response filed on 9/30/2009 has been received and entered into the case.

Claims 1, 2, 4 and 7 are canceled, claims 16 and 17 are newly added, and claims 3, 5, 6, 8-17 are pending and have been considered on the merits. All arguments have been fully considered.

The claim rejection under 35 U.S.C. §103 has been withdrawn due to the amendment.

#### ***Response to Amendment***

The declaration under 37 CFR 1.132 filed 9/30/2009 by Dr. Belhumeur is mainly focused on the argument showing significant difference between mammalian prion proteins used by Safar et al. and the claimed yeast prion-like proteins used in the instant invention. The argument is sufficient to show differences between mammalian prion proteins and yeast prion-like proteins.

Furthermore, it is not clear whether the listed yeast prion-like proteins are considered as "prion" protein per se. Based on the declaration, it appears that the applicant distinguish the yeast prion-like proteins from mammalian prion proteins. Although applicant also referred the yeast prion-like proteins as "yeast prion proteins" in the response, the Examiner interprets that the claimed yeast proteins as yeast prion-like proteins which are physically and chemically different from the mammalian prion proteins.

However, based on this evidence showing the significant difference between these two proteins, and the limited disclosure of the specification which lacks any disclosure and correlation such that the yeast prion-like proteins behave the same way as mammalian prion

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proteins upon a sterilization treatment, it is required that the instant claims are rejected based on enablement (see below).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 5, 6, 8-17 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether undue experimentation is required are summarized in *In re Wands*, 858 F.2d 731, 737, 8 USPQd 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. While all of these factors are considered, a sufficient number are discussed below so as to create a *prima facie* case.

The instant claims disclose a method of evaluating the efficiency of a sterilization process on prion proteins by using prion protein indicators synthesized from a yeast gene of SUP35, URE2 or HET-s. It is noted that the limitation of “prion proteins” in the amendment is considered as mammalian prion proteins since the yeast proteins are defined as “prion-like proteins” which are significantly different from mammalian prion proteins.

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The nature of the invention is that the yeast prion-like proteins would behave similarly, if not identical, upon a sterilization process as mammalian prion proteins, and thus, the level of degradation of the yeast prion-like proteins would be indicative of degradation of mammalian prion proteins.

Upon the declaration by Dr. Belhumeur on 9/30/2009, the yeast prion-like proteins claimed in the instant invention are significantly different physically as well as chemically, and behave differently from the mammalian prion proteins. The declaration as well as the response to the previous OA, applicant concluded that a person of ordinary skill in the art would not consider that the yeast prion-like proteins would behave the same way as the mammalian prion proteins (see declaration and the current response dated 9/30/2009 at p.11).

The specification does not provide any working evidence or direction given by the inventor that yeast prion-like proteins as claimed in the instant claims have any correlation in terms of degradation with mammalian prion proteins upon a sterilization treatment.

The state of the prior art is low, and it is highly unpredictable whether the yeast prion-like proteins behave the same way as mammalian prion proteins upon a sterilization treatment.

Thus, it is considered that the specification of the instant application does not describe subject matters in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.

### ***Conclusion***

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to TAEYOON KIM whose telephone number is (571)272-9041.

The examiner can normally be reached on 8:00 am - 5:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/  
Primary Examiner, Art Unit 1651